REMARKS

Applicants acknowledge receipt of a Non-Final Office Action ("Action") dated September 22, 2006. In this response Applicants amend claims 1-39. Following entry of these amendments, claims 1-39 are pending in the application.

No new matter has been introduced. Support for the amendments to the following claims can be found, e.g., in the following places in the publication of the instant application, U.S. App. Pub. No. 2005/0048519:

- recitation of "in-line screening capture device" in claims 1-23 – paragraph [0007];
- recitation of the cross-sectional area of the screening capture device's chambers in claims 1 and 24 – paragraph [0077];
- recitation of "in-line screening system" in claims 24-39 – paragraphs [0001], [0008], and [0058];
- claims 6 and 9 – paragraph [0044];
- claim 16 – paragraph [0050]; and
- claim 35 – paragraphs [0051] and [0083] and claim 19 as originally filed.

Reconsideration of the present application is respectfully requested in view of the foregoing amendments and the remarks which follow.

Objection to the Specification

On page 2 of the Action, the PTO asserts that the specification does not disclose "the inlet being connected via a collection duct, proximate to the collection needle." Applicants respectfully submit that the specification does provide such disclosure – see, e.g., Fig. 1B and paragraph [0043].

Objections to Claims

On page 3 of the Action, the PTO makes grammatical objections to claims 10, 25, and 39. These claims have been amended accordingly.

Rejections under 35 U.S.C. § 112, Second Paragraph

On page 3 of the Action, the PTO rejects claims 3 and 4 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants respectfully submit that a person of ordinary skill in the art (a "skilled artisan") would understand the meaning of the phrase, "the inlet of the screening capture device is connected, via a collection duct, proximate to the collection needle," in claims 3 and 4 – see, e.g., Fig. 1B and paragraph [0043].

On page 4 of the Action, the PTO asserts that claim 17 is indefinite because of the term "low density." Applicants respectfully submit that a skilled artisan would understand the meaning of the term "low density" in claim 17 – see, e.g., paragraphs [0047] and [0079].

Also on page 4 of the Action, the PTO asserts that claim 19 is indefinite because of the term "covalently attached analytes." Applicants respectfully submit that a skilled artisan would understand the meaning of the term "covalently attached analytes" in claim 19 – see, e.g., paragraphs [0045], [0048], [0051], and [0083].

Finally, on page 4 of the Action, the PTO claims that the term "the attached analytes" in claim 36 lacks antecedent basis. This rejection is moot in light of the amendment to claim 35.

In view of the foregoing amendments and remarks, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. §102 over Liu

On page 5 of the Action, claims 1-6, 10-17, and 22-39 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,924,107 to Liu ("Liu"). Under § 102, a single prior art reference can anticipate a claim only if it discloses, either expressly or inherently, each and every feature of the claim. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Further, "[d]uring examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference... between the claimed invention and the prior art. If so, the recitation serves to limit the claim." MPEP § 2111.02 (citing *In re Otto*, 312 F.2d 937, 938 (CCPA 1963)).

Applicants respectfully submit that Liu cannot anticipate any of the claims because Liu does not teach each and every feature of the claimed in-line screening capture device. For example, the statement of purpose or intended use in the preamble of claims 1 and 24, "for in-line screening of blood," imparts a structural feature to the claimed screening capture device – i.e., "results in a structural difference...between the claimed [device] and [Liu's device]" – in that the claimed device, unlike Liu's device, is *suitable* for use in in-line screening of blood. See, e.g., Figs. 1A, 1B, 2, 3 and 6, and paragraphs [0001], [0008], [0011], [0043], [0068], [0073], [0074] and [0077].

By contrast, Liu's device is *unsuitable* for screening blood as it is collected from a donor. For instance, Liu discloses no pumping mechanism and no system for drawing blood from a needle inserted into a donor, through a collection duct and screening capture device, and into a blood collection container. Instead, Liu merely discloses using a syringe pump to draw "bioelements" or "biosamples" from the wells of a microtiter plate into biochips to coat the biochips with the bioelements or to assay the biosamples. See col. 13, lines 27-32. In fact, Liu does not even mention the word "blood" at all. Rather, Liu's device is designed for high throughput screening of *prepared* samples. See, e.g., col. 3, lines 44-54; col. 4, lines 48-56 and 66-67; and col. 5, lines 1-5.

Importantly, Liu's device cannot achieve any of the flow rates for in-line screening of blood that are described in paragraph [0044] and recited in claims 7-9 of the instant application. To maintain a flow rate of about 450 mL per 10 minutes (the typical collection rate of the current apparatus used to collect blood) or a similar flow rate, "the dimensions of the screening capture device [] are designed so that it does *not slow down* the flow of blood. Thus, the screening capture device's [] chambers through which the blood flows are designed to have a cross-sectional area that is *no smaller* than that of the commonly used collection tube" (paragraph [0077], emphases added). The cross-sectional area of the device's chambers is recited in present claims 1 and 24.

In contrast, Liu's device is designed "to *reduce* the volume of the biosample solution in each [successive] capillary" by configuring subsequent arrayer capillaries "to have a *smaller* diameter than the [previous] arrayer capillaries." See col. 11, lines 57-67, and col. 12, lines 1-9 (emphases added). Therefore, Liu's device is incapable of achieving (1) a flow

rate of blood flowing through the device that is about 450 mL per 10 minutes, (2) a flow rate of blood flowing through the device that is no slower than the blood flow rate through the collection duct in the absence of the device, and (3) a constant flow rate of blood flowing though the device.

In sum, "the framework – the teachings of the prior art – against which patentability is measured is not all [screening capture devices] broadly, but [screening capture devices] *suitable* for use in [in-line screening of blood], for the claims are so limited." *In re Stencel*, 828 F.2d 751, 754 (Fed. Cir. 1987) (emphasis added). Since Liu's device is unsuitable for in-line screening of blood, Liu does not teach or suggest each and every feature of any of claims 1-6, 10-17, and 22-39. Further, with respect to claims 24-39, Applicants respectfully point out that what the PTO characterizes as a "biochip processor" in Liu, structure **60**, is actually a "channel". In fact, Liu does not even mention the word "processor" at all.

For the above reasons, Liu cannot anticipate any of the claims. Accordingly, Applicants respectfully request withdrawal of the rejections of claims 1-6, 10-17, and 22-39 under § 102(e) over Liu.

Rejections under 35 U.S.C. § 103

A *prima facie* case of obviousness has three requirements. First, a single prior art reference or a combination of references must teach or suggest each and every feature of the claimed invention. *In re Royka*, 490 F.2d 981, 984-85 (CCPA 1974). Second, there must be some reason, motivation, or suggestion to modify the single reference or combine the references in order to make the claimed invention. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). Third, the prior art must provide "a reasonable expectation of success" that modifying the single reference or combining the references would result in the claimed invention. *Id.* If any one of these three requirements is not met, a rejection for obviousness cannot stand.

1. Rejection over Liu in view of Chee

On page 12 of the Action, claim 18 is rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Liu in view of U.S. Pat. No. 5,861,242 to Chee *et al.* ("Chee"). Applicants respectfully submit that the combination of Liu and Chee does not satisfy all three

requirements for a *prima facie* case of obviousness. For example, the combination does not teach or suggest each and every feature of the claimed invention. As explained above, Liu's device is unsuitable for in-line screening of blood. Chee fails to remedy this deficiency. Moreover, neither Liu nor Chee suggests that "the first and second biochips comprise microarrays in which the analytes...are arranged along the length of the biochips in the direction of blood flow over the first and second biochips." Therefore, the combination of Liu and Chee cannot render claim 18 obvious.

Accordingly, Applicants respectfully request withdrawal of the § 103 rejection of claim 18 over Liu in view of Chee.

2. Rejections over Liu in view of Narang

On page 12 of the Action, claims 7-9, 19 and 21 are rejected under § 103(a) as allegedly being obvious over Liu in view of U.S. Pat. No. 6,020,209 to Narang *et al.* ("Narang"). Applicants respectfully submit that the combination of Liu and Narang does not satisfy all three requirements for a *prima facie* case of obviousness. For example, the combination does not teach or suggest each and every feature of the claimed invention. As explained above, Liu's device is unsuitable for in-line screening of blood. Narang fails to remedy this deficiency.

Moreover, with respect to claims 7-9, neither Liu nor Narang suggests the particular blood flow rate recited in any of these claims, and there is no motivation to combine Liu and Narang to achieve any of these blood flow rates. Regarding each of claims 7-9, the PTO asserts, "with the Liu biochip modified by Narang et al. to provide for a pump, the dimensions of the capillaries (**50**) in the Liu biochip is [*sic*] *capable* of allowing a flow rate as recited by Applicant" (page 14, Action, emphasis added). Even assuming *arguendo* the accuracy of such an assertion, Applicants respectfully note that the "fact that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish *prima facie* obviousness." MPEP § 2143.01.

In addition, with respect to claim 21, neither Liu nor Narang suggests "an anti-backflow device." Narang merely teaches that "valves could be used for fluid control" (col.

5, line 58), but does not teach that valves could be used to prevent fluid from flowing back toward a structure.

Because the combination of Liu and Narang does not satisfy all three requirements for a *prima facie* case of obviousness, the combination cannot render obvious any of claims 7-9, 19 and 21. Accordingly, Applicants respectfully request withdrawal of the § 103 rejections over Liu in view of Narang.

3. Rejection over Liu in view of Bashir and Yamanishi

On page 15 of the Action, claim 20 is rejected under § 103(a) as allegedly being obvious over Liu in view of U.S. App. Pub. No. 2001/0053535 to Bashir *et al.* ("Bashir") and U.S. App. Pub. No. 2003/0134416 to Yamanishi *et al.* ("Yamanishi"). Applicants respectfully submit that the combination of Liu, Bashir and Yamanishi does not satisfy all three requirements for a *prima facie* case of obviousness. For example, the combination does not teach or suggest each and every feature of the claimed invention. As explained above, Liu's device is unsuitable for in-line screening of blood. Bashir and Yamanishi fail to remedy this deficiency. Therefore, the combination of Liu, Bashir and Yamanishi cannot render claim 20 obvious.

Accordingly, Applicants respectfully request withdrawal of the § 103 rejection over Liu in view of Bashir and Yamanishi.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that all of the pending claims are now in condition for allowance. An early notice to this effect is earnestly solicited. If there are any questions regarding the application, the Examiner is invited to contact the undersigned at the number below.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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